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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,073	01/29/2001	Joseph G. Furst	X-13087	6899

7590 03/11/2004

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EXAMINER	
WOO, JULIAN W	

ART UNIT	PAPER NUMBER
3731	13

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,073	FURST, JOSEPH G.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication app ars on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *73-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 73-79 and 81-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. in view of Fearnot et al. (5,609,629). Israel et al. disclose an expandable intraluminal graft substantially as claimed. Israel et al. disclose, in figures 1-3, an expandable intraluminal graft (30) for use within a body cavity or blood vessel, where the graft has a body member having first and second ends, a wall or wall surface; first and second cross-sectional shapes, where the cross-sectional area of the second cross-sectional shape is greater than that of the first cross-sectional shape; the substantially same longitudinal length when the body member is in the first and second cross-sectional shapes (see col. 1, lines 52-54), first and second ends or end regions

having substantially smooth surfaces (17), and a biological agent at least partially and releasably coated on the surface of the body member (see col. 4, lines 33-36); where the wall surface is formed by a plurality of intersecting elongated members or wires (11, 12; see col. 4, lines 26-33), where the graft has at least one flexible connector (18) and two body members (see fig. 3), and where the body member is made of an etched, metal material visible under fluroscopy (see col. 4, lines 26-34),

However, Israel et al. do not disclose a biological agent including Trapidil and an intermediate, synthetic compound securing the biological agent to the body member, where the compound at least partially delays delivery of the biological agent into a body cavity; a body member at least partially coated with a material visible under fluroscopy, a body member at least partially treated with Gamma or Beta radiation, a biological agent for inhibiting or reducing restenosis, vascular narrowing, in-stent restenosis, and combinations thereof; and a biological agent including a platelet inhibitor. Fearnot et al. teach, in col. 7, lines 23-29 and col. 8, line 20 to col. 10, line 16, a graft with a body member (12) at least partially treated with a radiopaque coating; Gamma or Beta radiation or a biological agent for inhibiting or reducing restenosis, vascular narrowing, in-stent restenosis, and combinations thereof; a biological agent including a platelet inhibitor or Trapidil; and a body member with an intermediate, synthetic compound (porous layer 20 and/or coating layer 16) that at least partially delays delivery of the biological agent into a body cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Fearnot et al., to modify the graft of Israel et al. so that it has body members treated as claimed. Such a coated

graft would allow the introduction of bioactive or therapeutic materials into a body cavity. A radiopaque coating would allow location of the graft by fluroscopy.

3. Claims 80, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. in view of Fearnot et al. as applied to claims 73, 82, and 97 above, and further in view of March et al. (5,306,250). Israel et al. in view of Fearnot et al. disclose the invention substantially as claimed, but do not disclose a balloon for delivery of a biological agent from an interior of the balloon to the body cavity. March et al. teach, in col. 3, line 10 to col. 4, line 36, the application of a balloon for delivery of a biological agent from an interior of the balloon to the body cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a balloon as taught by March et al. with the graft of Israel et al. in view of Fearnot et al. It is well-known in the art that a graft may be implanted in a blood vessel after angioplasty. A balloon as taught by March et al. would be used, for example, to treat a lesion or injury in a blood vessel, which has undergone transluminal angioplasty, and thus prepare the vessel for receiving the graft of Israel et al. in view of Fearnot et al., which would further prevent restenosis and/or vessel constriction with a biological agent and mechanically maintain patency of the vessel with the body member.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Julian W. Woo
Primary Examiner

March 5, 2004